

APPENDIX 1

SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES

Contents

Overview	2
Decision Trees	
Written Description Amended or New Claims or Claims	
Asserting the Benefit of an Earlier Filing Date ...	4
Original Claims	5
Example 1: Amended claims	3
Example 2: 35 USC 120 Priority	6
Example 2A: Essential element missing	
from original claim	8
Example 2B: A preferred element missing from original claim	10
Example 3: New claims	12
Example 4: Original claim	15
Example 5: Flow Diagrams	17

Example 6: Genes	20
Example 7: EST	23
Example 8: DNA Fragment Encoding a Full length	
Open Reading Frame (ORF)	26
Example 9: Hybridization	28
Example 10: Process Claim	31
Example 11: Allelic Variant	33
Example 12: Bioinformatics	40
Example 13: Protein Variant	43
Example 14: Product by Function	46
Example 15: Antisense	49
Example 16: Antibodies	52
Example 17: Genus-species with widely varying	
species.....	54
Example 18: Process claim where the novelty is in the	

method steps	58
--------------------	----

Example 16: Antibodies

Specification: The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

Claim: An isolated antibody capable of binding to antigen X.

Analysis:

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

Conclusion: The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.